MEDICAL SCHOOL
UNIVERSITY OF MICHIGAN

KEVIN BOEHNKE, PH.D.
RESEARCH ASSISTANT PROFESSOR, ANESTHESIOLOGY

University of Michigan Medical School
Chronic Pain & Fatigue Research Center
24 Frank Lloyd Wright Dr., PO Box 385
Ann Arbor, Michigan 48105
(734) 998-6963
(734) 998-6900 fax
kboehnke@med.umich.edu

CRA Quarterly Progress Report: 10/01/2022 – 12/31/2022

Pragmatic Trial of Cannabidiol and Tailored Cannabis Coaching to Improve Chronic Pain Symptoms

Kevin F. Boehnke, PhD, Lead Principal Investigator
Rachel Bergmans, PhD, Co-Principal Investigator
Amy Bohnert, PhD, Co-Principal Investigator

1. **Percent of completion of the project objectives. This should include a brief outline of the work accomplished during the reporting period and the work to be completed during the subsequent reporting period.**

   The project completed a full quarter of work during after initiation in September 2022. We are still currently in startup, and have made considerable progress in the last three months of this award. Activities include:

   Approved Project Change – December 12/16/2022:
   As described in our 12/16/2022 update, we received approval to split up the sequential intervention study in our proposal into two separate interventions, so participants can choose to enroll in either the CBD or behavioral intervention. Each trial would intend to enroll n=468 participants, so we would still have the same number of Veterans completing each intervention. Those who complete the CBD study could then move on to the behavioral intervention trial if they wish. This study design modification did not change our proposed budget.

   Meetings:
   - We conduct weekly meetings with the study PIs (Drs. Boehnke, Bohnert, and Bergmans) and program managers to coordinate all portions of this large study and resolve any issues that arise each week.
   - We have had numerous ad hoc meetings with veteran partners to make connections with the community and gain insights and gather feedback for various aspects of the project.
   - Regular meetings with IT and regulatory personnel to lay framework for project launch in Spring/Summer 2023

   Personnel:
   - Vivian Kurtz was hired as the Program Manager on 10/17/2022. Ms. Kurtz helps oversee the project, write and revise study protocols, coordinate with regulatory bodies (e.g., Institutional Review Boards and the Food and Drug Administration), and help with overseeing study staff and procedures.
   - Study Coordinator: Completed interview process in late 2022 for a study coordinator.

- Research Assistant: A research assistant has been added to the project for help with a qualitative interview study that began in November 2022.
- Lead Health Education Coach: The position was posted in December 2022.
- Drs. Jenna McAfee and Evan Litinas were added to the project to aid with developing and manualizing the behavioral intervention.

Regulatory:

- Ahead of beginning the interventions and gaining project approvals by the UM IRBMed, the team is working with the Michigan Investigator Assistance Program (MIAP) at University of Michigan, which handles Investigational New Drug (IND) submission to the Food and Drug Administration (FDA) planned for a January 2023 submission in order to pilot the intervention in early 2023. Dr. Boehnke and Ms. Kurtz have met several times with the MIAP team and are finalizing materials for an IND submission for the CBD trial as well as determining the best route for review for the behavioral intervention.
- Registry Protocol: The Registry protocol was developed. The team has started the IRB application in preparation for institutional review and approval in early 2023.

Study Drug Update:

We have contacted DEA-licensed cannabis grow and processing facilities to find a source of cannabidiol (CBD) study medication that is derived from marijuana (i.e., cannabis with >0.3% THC). We have identified a vendor, Groff North America, a supplier of the CBD and placebo capsules. Our MIAP team is currently engaged with Groff North America to obtain the appropriate documentation for the IND submission.

Veteran and Community Engagement:

- **Interview Study:** To ensure that our behavioral intervention is informed by Veteran voices and current Veteran experiences with medical cannabis, the team is conducting a qualitative study of Veterans interested in or currently using medical cannabis. This will ensure representation of Veteran priorities within the development of the behavioral intervention and trail protocols. This study will also support our recruiting prospects and efforts for our clinical trials.

  For the goal of recruiting ~50 veteran participants, the team developed the protocol and materials in early November 2022 and received IRB approval/exemption for this interview study on November 22, 2022. Staff were trained and recruitment and interviews began in early December 2022. As of December 31, 2022, we have completed 9 interviews.

- **Project Branding:** The project team is working on branding the project and have engaged several Veterans and Veteran groups to provide feedback with regards to color, project logos, and project names.

- **Community Advisory Board:** The team continues to be in contact with several Veteran organizations, health care providers, scientist, policy makers, and Veterans throughout Michigan. Several have expressed interest to be included in the CAB and the team plans to hold the first CAB meeting in Q1 2023.

2. **Brief description of problems or delays, real or anticipated, which should be**

brought to the attention of the Grant Administrator.

- NA

3. **Statement concerning any significant deviation from previously agreed-upon Statement of Work.**

   - As described above, the approved project is now two separate clinical trials.
   - Our interview study was not explicitly described in the previously agreed-upon Statement of Work but it is an essential and inexpensive part of developing the behavioral intervention. Additionally, it is consistent with our community-engaged research approach, which is detailed in the original project proposal and includes evaluation of challenges and barriers to research participation among Veterans with chronic pain. These qualitative interviews with Veterans will ensure that our intervention is responsive to Veteran priorities and will aid with future recruitment for clinical trials as numerous participants have expressed interest in being contacted for those studies once they are available.

4. **Financial expenditures of grant money and other contributions to the project, in- kind and/or direct funding.**

   Funds were expended for personnel time and associated fringe benefits, consultant costs, software purchase, and subject incentives for the qualitative interview study.

   $58,569 – Direct Costs for Q4
   5,715 – Indirect Costs at 9.77%
   $64,284 – Total Q4 Expenditures

We look forward to continued progress on this project over the next quarter.

Sincerely,
Kevin F. Boehnke, PhD
Research Assistant Professor, Director of Controversial Compounds, Department of Anesthesiology
University of Michigan